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METHOD AND APPARATUS FOR USE IN ANCHORING A SUTURE

Background of the Invention

The present invention relates to a new and improved suture anchor inserter and a method of using the suture anchor inserter to position a suture anchor in either soft or hard body tissue.

Surgeons utilize suture anchor inserters to position suture anchors in either soft body tissue or hard body tissue. Suture anchor inserters for positioning suture anchors in soft or hard body tissue are disclosed in U.S. Patent Nos. 5,403,348; 5,464,426; and 5,549,630. During positioning of a suture anchor relative to body tissue, it may be necessary to form an opening in the body tissue to receive the anchor. Once the anchor has been received in the opening in body tissue, it may be desired to change the orientation of the anchor relative to the body tissue by pivoting or otherwise moving the anchor relative to body tissue.

Summary of the Invention

The present invention relates to a new and improved suture anchor inserter and method of using the suture anchor inserter. The suture anchor inserter includes a handle and a shaft which extends outward from the handle. The shaft has a leading end portion which extends into an anchor. The leading end portion of the shaft may extend through the anchor and be pointed to facilitate piercing of body tissue by the leading end portion of the shaft.

Once the anchor has been inserted into the body tissue, it may be desired to change the orientation of the anchor relative to the body tissue. The orientation of the anchor relative to the body tissue may be changed by applying force against an inner side surface of the anchor with the leading end portion of the shaft. In one embodiment of the inserter, a portion of the shaft is movable relative to another portion of the shaft to facilitate separation of the anchor and shaft. In another embodiment of the inserter, the shaft is formed as one piece. A spring may advantageously be utilized to hold the anchor on the leading end portion of the shaft.

Brief Description of the Drawings

The foregoing and other features of the present invention will become apparent to one skilled in the art to which the present invention relates upon consideration of the following description of the invention with reference to the accompanying drawings, wherein:

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Fig. 1 is a simplified schematic illustration of the manner in which an inserter constructed in accordance with the present invention may be utilized to insert an anchor into body tissue;

Fig. 2 is an enlarged fragmentary sectional view further illustrating the relationship between the anchor and a shaft of the inserter of Fig. 1;

Fig. 3 is a sectional view, taken generally along the line 3-3 of Fig. 2, illustrating the construction of the shaft of the inserter;

Fig. 4 is a schematic illustration depicting the manner in which the orientation of an anchor may be changed in the body tissue of Fig. 1 with the inserter;

Fig. 5 is a schematic illustration depicting the anchor of Fig. 4 after the anchor has been moved to a desired orientation in the body tissue;

Fig. 6 is a schematic illustration, generally similar to Fig. 1, illustrating a second embodiment of the inserter;

Fig. 7 is an enlarged fragmentary sectional view illustrating the relationship between an anchor and a one-piece shaft of the inserter of Fig. 6;

Fig. 8 is a sectional view, taken generally along the line 8-8 of Fig. 7, further illustrating the construction of the shaft of the inserter;

Fig. 9 is a schematic illustration depicting the manner in which the orientation of an anchor may be changed

in the body tissue of Fig. 6 with the inserter of Figs. 6-8; and

Fig. 10 is a schematic illustration depicting the relationship between a leading end portion of a shaft of a third embodiment of the inserter and an anchor.

Description of Specific Preferred Embodiments of the Invention

General Description

A suture anchor inserter 20 constructed and used in accordance with the present invention is illustrated in Fig. 1. The suture anchor inserter 20 includes a manually engageable handle 22 and a shaft 24 which extends from the handle. A leading end portion 26 (Fig. 2) of the inserter 20 extends through a passage 28 in a suture anchor 30. A suture 32 engages the anchor 30.

The illustrated anchor 30 has a cylindrical tubular side wall 36 (Fig. 2). A trailing end portion 38 of the anchor 30 has a flat annular trailing end surface 42. In addition, the anchor 30 has a leading end portion 44. The leading end portion 44 of the anchor 30 has an annular leading end surface 46.

The tubular side wall 36 of the anchor 30 has a cylindrical outer side surface 50 which extends between the trailing end surface 42 and the leading end surface 46. In addition, the illustrated anchor 30 has a cylindrical inner side surface 52 which is disposed in a coaxial relationship with the outer side surface 50. The cylindrical inner side

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surface 52 forms the passage 28 which extends between the trailing end surface 42 and leading end surface 46 of the anchor 30.

A groove or slot 56 is formed in the leading end portion 44 of the anchor 30. The groove or slot 56 extends axially inward from the leading end surface 46 and extends radially between the outer and inner side surfaces 50 and 52 of the anchor 30. The slot or groove 56 has an arcuately curving inner side surface 58 across which the suture 32 extends. It is contemplated that the slot or groove 56 may be omitted if desired.

The suture 32 has an outer leg 62 which extends along the outer side surface 50 of the anchor 30. An inner leg 64 of the suture 32 extends through the passage 28 and along the inner side surface 52 of the anchor 30. The outer leg 62 and inner leg 64 of the suture 32 are interconnected by a connector section 66 of the suture. The connector section 66 of the suture 32 extends through the slot 56 in the side wall 36 of the anchor 30. If the anchor 30 is constructed without the slot 56, the connector section 66 of the suture 32 would extend across the leading end surface 46 of the anchor.

The anchor 30 is made of a biocompatible material, specifically, stainless steel. The anchor 30 has a length, that is, the distance between the trailing end surface 42 and leading end surface 46, of approximately two millimeters. The anchor 30 has an outside diameter, that

is, the diameter of the outer side surface 50, of approximately one millimeter. The inner side surface 52 has a diameter of about one-half millimeter. It should be understood that the foregoing specific dimensions for one specific anchor 30 have been set forth herein only for purposes of clarity of description. It is contemplated that the anchor 30 will be constructed with dimensions which are different than the dimensions set forth above.

The illustrated anchor 30 has a cylindrical tubular side wall 36. It should be understood that the anchor 30 could have a different configuration. For example, the anchor 30 could have a polygonal cross sectional configuration if desired. Thus, the anchor 30 could have a polygonal configuration which is similar to the polygonal configuration of an anchor disclosed in U.S. Patent No. 5,549,630 issued September 27, 1996 to Peter M. Bonutti.

Although the anchor 30 is formed of metal, it is contemplated that the anchor 30 could be formed of other materials if desired. For example, the anchor 30 could be formed of body tissue. Alternatively, the anchor 30 could be formed of a polymeric material such as cellulose, petroylglutamic acid, collagen, or polylactide. It is believed that a ceramic as found in hydroxyapatite composites with polyethylene, polylactide or polyhydroxybutyrate may be utilized to form the anchor 30. If desired, the anchor 30 may be formed of a material which is hydrophilic and expands when exposed to body fluids.

In accordance with a feature of the present invention, the shaft 24 has a leading end portion 72 (Figs. 1 and 2) which is used to penetrate human body tissue. The leading end portion 72 of the shaft extends through the anchor 30. The leading end portion 72 of the shaft 24 may have a point 76 which extends ahead of the leading end surface 46 of the anchor 30.

The illustrated point 76 on the inserter shaft 24 has a conical configuration with a central axis which is coincident with a central axis of the inserter shaft and anchor 30. However, if desired, the point 76 could have a wedge-shaped configuration. Similarly, the point 76 could be formed by a single flat plane which is skewed at an acute angle to a longitudinal central axis of the shaft 24. Alternatively, the leading end of the shaft 24 could have a rounded or even a flat configuration.

The leading end portion 72 of the shaft 24 extends through the passage 28 in the anchor 30. The point 76 on the leading end of the shaft 24 is disposed ahead of and is coaxial with the anchor 30. This enables the point 76 to pierce body tissue ahead of the anchor 30. Although it is believed that the provision of the point 76 on the leading end of the shaft 24 will facilitate the piercing of human body tissue, the cross sectional size of the leading end of the shaft may be so small as to enable the shaft to pierce body tissue with a blunt end.

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By piercing the body tissue with the point 76, an opening is initially formed by the leading end portion 72 of the shaft 24. The shaft 24 moves the anchor into the opening which was initially formed by the point 76. The leading end surface 46 on the anchor 30 is sloped to form a continuation of a surface 80 on the point 76. The sloping leading end surface 46 on the anchor 30 promotes a smooth enlargement of the opening formed in the elastic material of the human body tissue by the point 76 on the leading end of the shaft 24. Although the point 76 is advantageously used to pierce soft body tissue, the inserter 20 may be used to position anchors 30 in preformed openings in hard body tissue, such as bone.

In accordance with another feature of the invention, the shaft 24 may be used to promote movement of the anchor 30 in human body tissue in such a manner as to change the orientation of the anchor relative to the body tissue and the shaft 24. Thus, it may be desired to change the orientation of the anchor 30 relative to the shaft 24 from the orientation shown in Fig. 1 to the orientation shown in Fig. 5. However, it should be understood that the inserter 20 may also be used to position suture anchors 30 which remain in the orientation shown in Fig. 1 relative to the body tissue.

When it is desired to change the orientation of an anchor 30 relative to body tissue, a leg 62 of the suture 32 is tensioned in the manner indicated by an arrow 84 in

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Fig. 4. At the same time, the point 76 on the shaft 24 engages the inner side surface 52 of the passage 28 through the anchor 30. This results in the application of a torque to the anchor 30 tending to rotate the anchor in a clockwise direction (as viewed in Fig. 4) from the orientation shown in Fig. 1 through the orientation shown in Fig. 4, toward the orientation shown in Fig. 5.

As this occurs, the cylindrical outer side surface 50 of the anchor is pressed against the elastic material of human body tissue 88 and deforms the body tissue. Once the anchor has been moved to the orientation shown in Fig. 5, pulling out of the anchor from the body tissue 88 is resisted by the relatively large outer side surface 50 of the anchor. This enables the anchor to remain stable in the body tissue 88 even though relatively large forces are applied to the legs 62 and 64 of the suture 32. Although the foregoing description has related to the changing of the orientation of the anchor 30 in soft body tissue, the inserter 20 may be used to change the orientation of an anchor in cancellous bone tissue in the same manner as previously set forth in association with soft body tissue.

Inserter

The suture anchor inserter 20 (Fig. 1) includes a handle 22 having a configuration suitable for manual grasping by a surgeon. The illustrated handle 22 has a generally cylindrical configuration with circumferentially extending grooves to facilitate firm gripping of the

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handle. However, if desired, the handle 22 could be formed with a generally triangular cross sectional configuration in a manner similar to that disclosed in U.S. Application Serial No. 08/673,923 filed July 1, 1996 and entitled "Suture Anchor Inserter Assembly and Method" by Peter M. Bonutti.

The shaft 24 extends axially outward from the handle 22. The shaft 24 has a generally cylindrical configuration and is disposed in a coaxial relationship with the handle 22. However, the shaft 24 could have a different configuration if desired. For example, if the passage 28 through the anchor 30 had a polygonal cross sectional configuration, the shaft 24 could have a corresponding polygonal cross sectional configuration.

In accordance with a feature of the embodiment of the inserter 20 illustrated in Figs. 1-3, the shaft 24 includes a cylindrical inner member 92 and cylindrical outer member 94 which are movable relative to each other. The upper (as viewed in Figs. 1 and 2) end of the solid cylindrical inner member 92 is fixedly connected with the handle 22. The point 76 is disposed on the lower (as viewed in Figs. 1 and 2) end of the inner member 92. The point 76 extends ahead of the leading end portion 44 of the anchor 30 to initiate formation of an opening into which the anchor moves.

As was previously mentioned, the point 76 could be formed with a configuration other than the illustrated conical configuration. In fact, it is contemplated that

the point 76 may be eliminated on some embodiments of the inserter. Although it is preferred to have the inner member 92 extend through the passage 28 and extend ahead of the leading end portion 44 of the anchor 30, the leading end of the inner member 92 could be disposed in the anchor if desired.

The outer member 94 has a tubular cylindrical configuration and partially encloses the solid inner member 92. The outer member 94 is axially movable relative to the inner member 92. The outer member 94 has a flat annular pusher surface 98 which engages the flat annular trailing end surface 42 of the anchor 30.

The inner and outer members 92 and 94 are both formed of metal, specifically stainless steel. However, the inner and outer members 92 and 94 could be formed of other materials if desired. For example, the inner member 92 could be formed of metal and the outer member 94 could be formed of a polymeric material.

The outer member 94 is axially movable along the inner member 92 between a retracted position, shown in Figs. 1 and 2, and a fully extended position in which the pusher surface 98 is adjacent to the lower (as viewed in Fig. 2) end of the point 76. Thus, the outer member 94 is movable axially along the inner member 92 from the position shown in Figs. 1 and 2 through the position shown in Fig. 4 to a position in which the annular pusher surface 98 is a short distance past the outer end of the point 76.

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A slot or groove 102 (Fig. 3) extends through a tubular cylindrical side wall of the outer member 94. The straight slot or groove 102 in the outer member 94 extends between opposite ends of the outer member 94 and is axially aligned with a passage which extends through the handle 22. The two legs 62 and 64 of the suture 32 extend through the slot 102 and the passage in the handle 22 to a location disposed above (as viewed in Fig. 1) the handle.

The inner leg 64 of the suture 32 extends through the passage 28 (Fig. 2) in the anchor 30. The leading end portion of the inner member 92 also extends through the passage 28 in the anchor 30. In the illustrated embodiment of the inserter 20, a straight slot or groove 106 extends axially along the inner member 92 from the point 76 to a location which is disposed above (as viewed in Fig. 2), the pusher surface 98 when the outer member 94 is in the retracted position. The inner leg 64 of the suture then extends from the slot 106 in the inner member 92 into the slot 102 in the outer member 94. The slot 106 in the inner member 92 terminates at a location disposed axially above (as viewed in Fig. 2) the pusher surface 98 when the pusher surface is in the retracted position.

An actuator 110 is provided to move the outer member 94 axially along the inner member 92. The actuator 110 (Fig. 1) includes a manually engageable knob or input member 112 which is connected to the outer member 94 and extends through a slot 114 formed in the handle 22. The

slot 114 has an axial extent which corresponds to the distance which the outer member 94 can be moved axially along the inner member 92. When the outer member 94 is in the fully retracted position of Fig. 1, the knob 112 is adjacent to an upper end of the slot 114.

After the anchor 30 has been moved into body tissue 88 and is to remain in the orientation shown in Fig. 1, the actuator knob 112 is moved downward (as viewed in Fig. 1) in the slot 114. As this occurs, force is transmitted between the pusher surface 98 and the trailing end surface 42 of the anchor 30. At the same time, the shaft 24 may be moved straight upward (as viewed in Fig. 1).

The relative movement between the anchor 30 and inner member 92 results in the trailing end surface 42 of the anchor 30 being moved in alignment with the base or upper end of the point 76. When this has happened, a cylindrical outer side or positioning surface 120 on the inner member 92 is disposed above (as viewed in Fig. 2) the annular trailing end surface 42 of the anchor 30. Continued relative movement between the inner and outer members 92 and 94 at least partially withdraws the point 76 from the passage 28 in the anchor 30. The handle 22 of the inserter 20 can then be moved or pulled upward away from the body tissue 88 and the point 76 of the shaft 24 moved completely out of the anchor 30. This results in the anchor 30 remaining in the orientation shown in Fig. 1 in the body tissue 88.

As the outer member 94 is moved axially downward (as viewed in Figs. 1 and 2) to separate the anchor from the shaft 24, the extent of the telescopic relationship between the portions of the inner and outer members 92 and 94 disposed in the handle 22 is decreased. Thus, when the outer member 94 is in the fully retracted position shown in Fig. 1, the extent to which the portion of the inner member 92 disposed in the handle is enclosed by the outer member 94 is a maximum. As the actuator knob 112 is moved downward (as viewed in Fig. 1) in the slot 114, a portion of the outer member 94 moves out of the handle 22 and the extent of the telescopic relationship between the inner and outer members 92 and 94 in the handle 22 decreases.

The length of the slot 114 is great enough to enable the pusher surface 98 to move along the length of the point 76. When the actuator knob 112 has reached the lower end (as viewed in Fig. 1) of the slot 114, the upper end portion of the outer member 94 is still in the handle 22. At this time, the pusher surface 98 has moved to a location just past the point 76. Therefore, the point 76 is fully enclosed by the outer member 94.

It should be understood that a surgeon using the inserter 20 can determine the extent of relative movement between the inner and outer members 92 and 94. The surgeon may move the actuator knob 112 through only a portion of the length of the slot 114. Suitable indicia may be

provided along the slot 114 to indicate the position of the pusher surface 98 relative to the point 76.

In the embodiment of the invention illustrated in Fig. 1, the actuator knob 112 is connected directly with the outer member 94 and is movable in the slot 114 in the handle 22. However, it is contemplated that the actuator knob 112 and the slot 114 could be eliminated and suitable knurling and/or projections provided on the outer member 94. The knurling or projections on the outer member 94 may be manually engaged and force transmitted directly from the hand of a surgeon to the outer member. If force is to be manually applied directly to the outer member 94, the outer member could either extend into the handle 22 or terminate short of the handle.

Insertion of Anchor

When the anchor 30 is to be inserted into body tissue 88, the suture 32 extends through the passage 28 in the anchor 30. The legs 62 and 64 of the suture 32 extend along the slot 102 in the outer member 94 and through the passage (not shown) in the handle 22. However, if desired, the legs 62 and 64 of the suture 32 could extend along the outside of the shaft 24 and handle 22.

The anchor 30 is then positioned on the leading end portion 26 of the inserter 20 with the suture 32 extending through the passage 28 in the anchor and with the outer member 94 in the retracted position of Figs. 1 and 2. It should be understood that the suture 32 could be connected

with the anchor 30 in a manner other than by extending through the passage 28. For example, an opening could be provided in the anchor 30 at a location spaced from the passage 28. The suture 32 could extend through or be tied off at this opening.

To position the anchor 30 on the leading end portion 26 of the shaft 24, the point 76 on the inner member 92 is inserted into the passage 28 in the anchor 30. The slot 106 in the inner member 92 is aligned with the inner leg 64 of the suture. The anchor is then moved along the inner member 92 until the trailing end surface 42 on the anchor moves into abutting engagement with the pusher surface 98 on the outer member 94. At this time, the point 76 on the inner member 92 extends outward from and is coaxial with the end surface 46 of the anchor 30. The suture 32 is then tensioned to hold the anchor 30 in place.

The point 76 on the inner member 92 is then moved into engagement with an imperforate outer surface 130 (Fig. 1) on a human patient's skin 132. Manual force is applied to the handle 22 to cause the point 76 on the inner member 92 to pierce the surface 130. As this occurs, a circular opening is formed in the skin 132 by the point 76 of the inner member 92. This opening is formed directly ahead of and in axial alignment with the anchor 30.

The manual application of downward (as viewed in Fig. 1) force against the handle 122 moves the point 76 of the inner member 92 through the skin 132 into flesh 134

disposed beneath the skin. As this occurs, the leading end portion 44 of the anchor 30 moves into the opening which was initially formed by the point 76 on the inner member 92. The annular pusher surface 98 on the outer member 94 presses against the annular trailing end surface 42 of the anchor 30 to push the anchor into the body tissue.

Movement of the leading end portion 44 of the anchor 30 into the opening formed by the point 76 in the body tissue is facilitated by having at least a portion of the leading end surface 46 of the anchor 30 slope radially outward as a continuation of the surface 80 on the point 76. As the leading end 44 of the anchor 30 is pressed against the viscoelastic body tissue 88, the initial opening is elastically expanded and the anchor 30 moves into the flesh 134 disposed beneath the skin 132. The point 76 pierces the flesh 134 ahead of the anchor 30 to initiate the formation of an opening in the flesh for the anchor.

Continued application of force to the handle 22 results in the shaft 24 moving the anchor 30 to a desired depth in the body tissue 88. As this occurs, the point 76 on the inner member 92 continues to penetrate or pierce the body tissue 88 ahead of the anchor 30. This facilitates movement of the shaft 24 and anchor 30 into the body tissue 88.

The anchor 30 is moved into the body tissue 88 under the influence of force transmitted from the pusher surface

98 on the outer member 94 to the trailing end surface 42 of the anchor. Thus, as the shaft 24 and anchor 30 move into the body tissue 88, the outer member 94 is stationary relative to the inner member 92. The pusher surface 98 on the outer member 94 presses against the trailing end portion 38 of the anchor 30 with a force sufficient to move the anchor into the body tissue 88.

Once the anchor 30 has been moved into the body tissue 88, the anchor and shaft 24 are separated. When this is to be done, any tension in the legs 62 and 64 of the suture is eliminated. The actuator knob 112 is then moved downward (as viewed in Fig. 1) along the slot 114. As this occurs, relative movement between the anchor 30 and the inner member 92 results in the point 76 (Fig. 2) on the inner member being circumscribed by the tubular side wall 36 of the anchor.

When the anchor 30 is being separated from the inserter 20, the anchor may be pushed off of the end of the inner member 92 by the outer member 94 while the inner member remains stationary relative to the body tissue. Alternatively, the handle 22 and inner member 92 may be moved upwardly and the anchor 30 and outer member 94 maintained stationary relative to the body tissue. It is contemplated that, in all probability, there will be a combined movement of the anchor 30 and outer member 94 axially along the inner member 92 and withdrawal of the

inner member from the body tissue as the anchor is separated from the shaft 24.

Changing Anchor Orientation

As the anchor 30 is separated from the shaft 24, it may remain in the orientation shown in Fig. 1 relative to the body tissue 88 and the shaft. Alternatively, the anchor 30 may be moved through the orientation shown in Fig. 4 to the orientation shown in Fig. 5. At least a portion of this movement of the anchor 30 occurs while the leading end portion 26 of the inserter 20 is in the passage 28 in the anchor.

During movement of the anchor 30 to a desired depth in the body tissue 88 (Fig. 1), the outer side surface 120 on the inner member 92 positions the anchor in a coaxial relationship with the inner member 92 and retains the anchor against pivotal movement. When the anchor 30 has been moved to the desired depth in the body tissue 88, the actuator 110 is manually operated. This causes relative movement between the inner and outer members 92 and 94.

As relative movement occurs between the inner and outer members 92 and 94, the point 76 on the outer member and the pusher surface 98 on the inner member move toward each other (Fig. 4). As this occurs, the positioning surface 120 on the inner member 92 almost moves out of the passage 28 in the anchor 30 (Fig. 4). This releases the anchor 30 for pivotal movement relative to the shaft 24. Although a major portion of the positioning surface 120 has

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been withdrawn from the anchor passage 28, the point 76 on the inner member 92 and the outermost portion of the positioning surface 120 are disposed in the passage 28 in the anchor.

Pivotal movement of the anchor 30 is then initiated by tensioning the outer leg 62 of the suture 32, as indicated by the arrow 84 in Fig. 4. The tension force applied to the leading end portion 44 of the anchor 30 causes it to rotate in a clockwise direction toward the position shown in Fig. 4. As the anchor approaches the position shown in Fig. 4, the inner side surface 52 on the anchor 30 moves into engagement with the outer side surface 80 on the point 76. This results in the transmittal of force from the outer side surface 80 of the point 76 to the inner side surface 52 of the anchor 30 in a downward (as viewed in Fig. 4) direction to further promote pivotal movement of the anchor in a clockwise direction.

As the outer member 94 continues to push downward (as viewed in Fig. 4) against the trailing end surface 42 of the anchor 30, the anchor continues to pivot relative to the shaft 24. The anchor 30 pivots about a location where the trailing end surface 42 of the anchor engages the outer member 94. In addition, the anchor 30 pivots about a location where the point 76 engages the inner side surface 52 of the anchor. This combined pivotal movement is caused by the tension in the outer leg 62 of the suture 32.

As the pusher surface 98 approaches and then moves past the base of the point 76, the point moves out of the passage 28 through the anchor 30. The anchor 30 then continues to pivot in a clockwise direction under the influence of the force applied to the anchor by the tension in the outer leg 62 of the suture 32. This force causes the anchor to move to the position shown in Fig. 5, or at least to a position closely approximating the position shown in Fig. 5. Once the anchor 30 has moved to the position shown in Fig. 5 relative to the body tissue 88, the relatively large outer side surface 50 of the anchor resists pulling out of the anchor from the body tissue. Therefore, relatively large forces can be transmitted through the suture 32 to the anchor 30 without pulling the anchor out of the body tissue.

When the anchor 30 is to be inserted into bone with the inserter 20, an opening is drilled through the hard outer layer of the bone into the soft inner material of the bone. Once this has been done, the inserter 20 is used to position the anchor 30 in the spongy cancellous tissue within the bone. The orientation of the anchor 30 may be changed, relative to the bone, in the same manner as previously explained herein.

It should be understood that it is contemplated that the inserter 20 may be used to position an anchor 30 in either hard or soft tissue at many different locations in a patient's body. The pointed end 76 of the inserter 20 may

be used to pierce body tissue at locations remote from the patient's skin 132 (Fig. 1). Thus, the inserter 20 may be used to position an anchor in an organ disposed within the patient's body.

When the inserter 20 is to be used to position the anchor 30 in a preformed opening in hard body tissue, such as the hard outer or cortical layer of bone, the inner member 92 may not extend past the leading end portion 44 of the anchor 30. When the inserter 20 is to be used to position the anchor 30 in soft body tissue, the formation of an opening in the body tissue for the anchor 30 may be accomplished without piercing the body tissue with the inner member 92 and the inner member may not extend past the anchor. However, it is believed that it may be preferred to have the point 76 extend ahead of the anchor 30 even when the point is not to be used to pierce body tissue.

Inserter - Second Embodiment

In the embodiment of the inserter illustrated in Figs. 1-5, the shaft 24 is formed by two members, that is, the inner member 92 and the outer member 94. In the embodiment of the inserter illustrated in Figs. 6-9, the shaft of the inserter is formed by a single member. Since the embodiment of the invention illustrated in Figs. 6-9 is generally similar to the embodiment of the invention illustrated in Figs. 1-5, similar numerals will be utilized to designate similar components, the suffix letter "a"

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being associated with the numerals of Figs. 6-9 to avoid confusion.

A suture anchor inserter 20a (Fig. 6) includes a manually engageable handle 22a and a one piece shaft 24a which extends outward from the handle. A leading end portion 26a of the one piece shaft 24a extends through a passage 28a in the suture anchor 30a. A suture 32a extends through the passage 28a in the anchor 30a and along the shaft 24a. The suture 32a extends through a passage (not shown) in the handle 22a. The anchor 30a has the same construction as the anchor 30 in the embodiment of the invention illustrated in Figs. 1-5.

In accordance with a feature of the embodiment of the invention illustrated in Figs. 6-9, the shaft 24a of the inserter 20a is formed as one piece. Thus, the shaft 24a includes a main section 142 (Figs. 6 and 7) and a leading end section 144 (Fig. 7). The leading end section 144 includes a cylindrical positioning portion 146 which is disposed in a coaxial relationship with the cylindrical main section 142. A generally conical point 76a is formed on the leading end section 144 and has a conical outer side surface 80a.

A pusher surface 98a forms a flat annular shoulder where the cylindrical main section 142 is connected with the leading end section 144 of the shaft 24a. Since the shaft 24a is formed from a single piece of material, that is, stainless steel, the pusher surface 98a does not move

relative to the point 76a of the shaft 24a. Although it is preferred to form the shaft 24a from a single piece of metal, the shaft may be formed by a solid cylindrical inner member and a cylindrical tubular outer member which is fixedly connected to the inner member. When the shaft 24a is formed by two fixedly connected members, the members may be different materials.

A slot 102a (Figs. 7 and 8) extends from the base of the point 76a along the shaft 24a. The depth of the slot 102a is greater in the main section 142 (Fig. 7) of the one piece shaft 24a than in the leading end section 144 of the shaft. The inner and outer legs 62a and 64a of the suture 32a are received in the slot 102a (Fig. 8).

When the anchor 30a is to be inserted into human body tissue 88a (Fig. 6), the anchor is first positioned on the leading end section 144 of the shaft 24a with the suture 32a extending through the passage 28a in the anchor 30a. Thus, the anchor 30a is telescopically moved onto the positioning portion 146 of the leading end section 144 of the shaft 24a. As this occurs, a trailing end surface 42a on the anchor 30a is positioned in abutting engagement with the annular pusher surface 98a.

A cylindrical outer side surface 120a on the positioning portion 146 engages a cylindrical inner side surface 52a of the anchor 30a (Fig. 7). The positioning surface 120a on the leading end section 144 of the shaft 24a positions the anchor 30a in a coaxial relationship with

the shaft 24a and the point 76a. The two legs 62a and 64a of the suture 32a are tensioned to hold the trailing end surface 42a of the anchor 30a in abutting engagement with the pusher surface 98a on the shaft 24a.

The point 76a on the leading end section 144 of the shaft 24a is then moved into engagement with an imperforate outer surface 130a (Fig. 6) of a human patient's skin 132a. A downward force is then manually applied to the handle 22a. This force causes the point 76a on the shaft 24a to pierce the outer side surface 130a of the skin 132a. The point 76a then moves into flesh 134a disposed beneath the skin. As this occurs, an opening is formed by the point 76a in the skin 132a.

The anchor 30a moves into the opening in the skin 132a. Force is applied against the trailing end surface 42a of the anchor 30a by the pusher surface 98a to push the anchor into the body tissue 88a. A leading end surface 46a on the anchor 30a is sloped so as to form a continuation of the outer side surface 80a of the point 76a. This results in a smooth enlargement or stretching of the circular opening which is initially formed in the skin 132a by the point 76a of the shaft 24a. As the shaft 24a and anchor 30a continue to move downward (as viewed in Fig. 6) into the flesh 134a beneath the skin 132a, the point 76a on the shaft 24a pierces the body tissue to facilitate movement of the anchor 30a into the body tissue.

Once the anchor 30a has been moved to the desired depth in the body tissue, the anchor is separated from the shaft 24a. This may be done by merely withdrawing the leading end section 144 of the shaft 24a from the anchor 30a while the anchor remains in the orientation shown in Fig. 6 in the body tissue 88a. It is contemplated that there will be relatively little friction between the outer side surface 120a on the positioning portion 146 of the shaft 24a and the inner side surface 52a. This enables the anchor to be held in position in the body tissue 88a by the resilient force applied against the anchor 30a by the body tissue as the inserter 20a is withdrawn from the anchor.

It is contemplated that it may be desired to apply force against the trailing end surface 42a of the anchor 30a to facilitate separation of the shaft 24a from the anchor 30a. If this is the case, a cylindrical pusher rod 150 (Fig. 7) may be provided in a suitable passage formed in the solid shaft 24a. An actuator 110a has a knob 112a which is connected with the pusher rod 150 and is movable along a slot 114a formed in the handle 22a.

When the shaft 24a is to be withdrawn from the anchor 30a, the actuator knob 112a is moved downward. This results in the pusher rod 150 moving downward (as viewed in Fig. 7) relative to the shaft 24a. A circular leading end surface on the pusher rod 150 applies force against the trailing end surface 42a of the anchor to facilitate separation of the shaft from the anchor. It should be

understood that the pusher rod 150 is optional and may be omitted if desired.

It is believed that in certain situations at least, it will be desired to change the orientation of the anchor relative to the body tissue 88a and the shaft 24a as the shaft 24a and anchor 30a are separated. To accomplish this, the leg 62a of the suture 32a is tensioned, in the manner indicated by the arrow 84a in Fig. 9 as the shaft 24a is withdrawn from the anchor. This results in pivoting movement of the anchor relative to the shaft 24a in the same manner as previously explained in conjunction with the embodiment of the invention illustrated in Figs. 1-5.

It is believed that the use of the pusher rod 150 to apply force against a side of the anchor 30a opposite from the suture 32a will promote pivoting movement of the anchor. In addition, pivoting movement of the anchor 30a is promoted by engagement of the outer side surface 80a on the point 76a of the shaft 24a with the inner side surface 52a of the anchor. It should be understood that the anchor 30a moves through the orientation shown in Fig. 9 to the orientation shown in Fig. 5 for the anchor 30.

It is contemplated that the point 76a may have a configuration which is different than the illustrated conical configuration. For example, the point 76a could be formed by a single flat side surface which is skewed relative to a central axis of the shaft 24 or by a plurality of skewed flat side surfaces which intersect at

the central axis of the shaft. Alternatively, the end of the end section could have a blunt or flat configuration rather than the illustrated pointed configuration.

Third Embodiment of Inserter

In the embodiments of the inserter illustrated in Figs. 1-9, the anchor is retained on the shaft of the inserter prior to insertion of the anchor into body tissue by tensioning the suture. In the embodiment of the invention illustrated in Fig. 10, the inserter includes a spring which is utilized to retain the anchor on the shaft of the inserter. Since the embodiment of the invention illustrated in Fig. 10 is generally similar to the embodiments of the invention illustrated in Figs. 1-9, similar numerals will be utilized to designate similar components, the suffix letter "b" being associated with the numerals of Fig. 10 to avoid confusion.

An inserter 20b (Fig. 10) includes a handle (not shown) and a shaft 24b which extends outward from the handle. The shaft 24b is integrally formed from a single piece of metal, that is, stainless steel. The shaft 24b includes a relatively large diameter main section 142b and a relatively small diameter leading end section 144b. The leading end section 144b includes a positioning portion 146b on which a conical point 76b is disposed in a coaxial relationship with the main section 142b of the shaft 24b. An annular pusher surface 98b is formed at the junction

between the main section 142b and positioning portion 146b of the shaft 24b.

A suture 32b has an outer leg 62b which extends along the outside of an anchor 30b. In addition, the suture 32b has an inner leg 64b which extends through a passage 28b in the anchor 30b. The leading end section 144b and the inner leg 62b of the suture 32b both extend through the passage 28b in the anchor 30b.

In accordance with a feature of this embodiment of the invention, a spring 160 extends through a passage in the shaft 24b. The illustrated spring 160 is formed of metal wire, However, the spring 160 could be a leaf spring formed of sheet metal if desired.

An upper end portion (not shown) of the wire spring 160 is connected with an actuator knob, corresponding to the actuator knobs 112 and 112a of the embodiments of the invention illustrated in Figs. 1-9. The spring 160 has a bent portion 164 which engages an inner side surface 52b of the anchor 30b.

After the anchor 30b has been inserted into body tissue, in the manner described in conjunction with the embodiment of the invention illustrated in Figs. 1-9, the spring 160 is axially tensioned. To axially tension the spring 160, the actuator knob is moved away from the leading end section 144b of the shaft 24b. The axial tension causes the bent portion 164 of the spring 160 to straighten and move out of engagement with the inner side

surface 52b of the passage 28b in the anchor 30b. The shaft 24b can then be withdrawn from the anchor 30b.

It is preferred to move the bent portion 164 of the spring 160 out of engagement with the inner side surface 52b of the anchor 30b by resiliently flexing the spring. However, the tension force applied to the spring 160 may only effect a reduction in the force applied by the spring against the inner side surface 52b of the anchor 30b.

In the embodiment of the invention illustrated in Fig. 10, the anchor 30b and one-piece shaft 24b are separated by merely withdrawing the shaft from the anchor after it has been positioned in a desired location in body tissue. However, a pusher member, corresponding to the pusher rod 150 of the embodiment of the invention illustrated in Figs. 6-9 could be utilized to promote separation of the anchor 30b from the shaft 24b if desired. Alternatively, the shaft 24b could be formed by two relatively movable members, corresponding to the inner and outer members 92 and 94 of the embodiment of the invention illustrated in Figs. 1-5. Of course, the orientation of the anchor 30b can be changed relative to the shaft 24b by tensioning the leg 64b of the suture 32b as the point 76b of the shaft 24b moves to a location adjacent to the trailing end surface 42b of the anchor.

Conclusion

In view of the foregoing description, it is apparent that the present invention provides a new and improved

suture anchor inserter 20 and method of using the suture anchor inserter. The suture anchor inserter 20 includes a handle 22 and a shaft 24 which extends outward from the handle. The shaft 24 has a leading end portion 72 which extends into an anchor 30. The leading end portion 72 of the shaft 24 may be pointed to facilitate piercing of body tissue 88 by the leading end portion of the shaft.

Once the anchor 30 has been inserted into the body tissue 88, it may be desired to change the orientation of the anchor relative to the body tissue. The orientation of the anchor 30 relative to the body tissue 88 may be changed by applying force against an inner side surface 52 of the anchor with the leading end portion 72 of the shaft 24. In one embodiment (Figs. 1-5) of the inserter 20, a portion 94 of the shaft 24 is movable relative to another portion 92 of the shaft to facilitate separation of the anchor 30 and shaft. In the embodiment of the inserter illustrated in Figs. 6-9, the shaft 24a is formed as one piece. A spring 160 (Fig. 10) may advantageously be utilized to hold the anchor 30 on the leading end portion of the shaft 24.